IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 1 CASES LISTED ON EXHIBIT A**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF BRIAN N. SCHWARTZ, M.D.

Plaintiffs file this reply in support of their motion to exclude certain expert testimony proffered by Defendants Johnson & Johnson, Inc. and Ethicon, Inc.'s ("Ethicon") expert Brian N. Schwartz, M.D. ("Dr. Schwartz"), Ethicon's general causation expert in cases involving the TVT-O and the TVT-Secur.[1] In support, Plaintiffs shows the Court the following:

Plaintiffs moved earlier to exclude or limit the testimony of Ethicon's expert, urologist Dr. Schwartz. To avoid repetition, Plaintiffs incorporate and reurge the contents of their motion and memorandum in support here. In opposition, Ethicon attempts to cast Dr. Schwartz's opinions and testimony in an admissible light. But it cannot overcome the unreliability of his opinions; nor can it overcome this Court's prior rulings consistently disallowing testimony of the same kind Ethicon attempts to offer through Dr. Schwartz.

ARGUMENT

[1] *See* Exhibit A for a list of all the TVT-O and TVT-S cases in which Dr. Schwartz has been identified as a general causation expert.

I. DR. SCHWARTZ'S OPINIONS REGARDING THE MATERIAL PROPERTIES OF TVT-O AND TVT-SECUR MESH SHOULD BE EXCLUDED

Ethicon argues that this Court's Order in *Huskey* supports its contention that Dr. Schwartz is qualified to opine on the material properties of the TVT-O and TVT-Secur.[2] Ethicon argues that Dr. Schwartz's qualifications are analogous to those of Dr. Harry Johnson and Dr. Bruce Rosenzweig, whom were both found qualified by this Court to opine on mesh degradation and particle loss, and as a result, Dr. Schwartz should also be qualified to so opine.[3] Ethicon's claims are misplaced.

Dr. Johnson has performed more TVT and TVT-O implants than Dr. Schwartz.[4] While Dr. Schwartz has performed a similar amount of mesh revision surgeries as Dr. Johnson, Dr. Johnson has otherwise treated patients with mesh-related complications.[5] More importantly, this Court determined that Dr. Johnson was qualified based on his research *coupled with* his clinical experience, not his clinical experience alone.[6] Dr. Johnson is a co-principal investigator and founding member of the Urinary Incontinence Treatment Network ("UITN").[7] Under the UITN's directions, he "conducted several randomized, surgical trials comparing different treatments for urinary incontinence including fascial slings, Burch colposuspension, and mid-urethral synthetic slings, including the TVT, TVT–O, and Monarc slings."[8] Dr. Schwartz does not have remotely similar research experience. Dr. Schwartz's qualifications are not analogous to Dr. Johnson's.

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[2] *Huskey v. Ethicon, Inc*., 29 F.Supp.3d 691 (S.D. W. Va. 2014). Ethicon Response at 2-4.
[3] *Huskey*, 29 F.Supp. 3d at 707, 734. Ethicon Response at 2-4.
[4] *Huskey*, 29 F.Supp.3d at 734. ("Dr. Johnson has implanted at least 750 TVT or TVT–O devices.") Ethicon Response at 1. ("Dr. Schwartz. . .has performed over 600 surgical implantations of synthetic mid-urethral slings—hundreds of which involved Ethicon's TVT-O or TVT-Secur products.")
[5] *Huskey*, 29 F.Supp 3d at 734. Ethicon Response at 2.
[6] *Huskey*, 29 F Supp 3d at 734. ("Accordingly, I FIND that Dr. Johnson's ***research and clinical experience*** qualifies him to render opinions regarding the lack of mesh degradation and particle loss.") (Emphasis added).
[7] *Id.*
[8] *Id.*

The Court in *Winebarger v. Boston Scientific Corp.*[9] excluded the opinions of Dr. Patrick Culligan regarding mesh properties including pore size, shrinkage, foreign body response and degradation. Though the Court found that Dr. Culligan considered the scientific literature, Dr. Culligan's deposition testimony revealed he relied heavily, if not primarily, on his clinical experience in forming his opinions. Dr. Schwartz also relies primarily on his clinical experience rather than any expertise developed outside of litigation. Dr. Schwartz readily admitted that he had not studied polypropylene or mesh in the same way that a polymer scientist might.[10] Dr. Schwartz has never designed mesh and has no training as a medical device engineer.[11] Dr. Schwartz is not a pathologist.[12] Dr. Schwartz has only viewed mesh grossly upon explant and has not analyzed explanted mesh under the microscope.[13] In relation to mechanical-cut vs. laser-cut mesh, Dr. Schwartz offers the opinions that laser cut mesh is "state of the art" and that "I have not found there to be a clinically significant difference in the way the mesh itself performs."[14] Dr. Schwartz bases these opinions on his personal experience, yet he has made absolutely no effort to track and evaluate patient outcomes to actually evaluate his clinical experience.[15] Dr. Schwartz states that literature supports mechanically-cut mesh, but acknowledges that medical literature does not differentiate between laser-cut and mechanically-cut mesh.[16] Dr. Schwartz fails to employ reliable methodology in reaching his opinions on mesh material properties and they should be excluded just as Dr. Culligan's were in *Winebarger*.

[9] *Winebarger v. Boston Scientific Corp.*, 2015 WL 1509362, at 35 (S.D. W. Va. April 1, 2015).
[10] *See* Ex. E at 76:13-77:1.
[11] Ex. E at 67:8-12.
[12] Ex. E at 76:13-77:11.
[13] Ex. E at 76:13-14; 77:7-11.
[14] Ex. B at 28.
[15] Ex. E at 65:1-23.
[16] Ex. E at 68:8-69:6.

Further, Ethicon contends Plaintiffs have not identified design opinions similar to those at issue in *Tyree*, and as a result, *Tyree* is inapplicable to the case at bar. This is incorrect. Plaintiffs' motion lays out Dr. Schwartz's unqualified and unreliable design opinions and testimony, specifically regarding pore size and mesh density used in the TVT-O and TVT-Secur as well as his design opinions related to mechanical-cut v. laser-cut mesh, and fraying, curling and roping.[17] In *Tyree*, Dr. Jerry Blaivas's opinions regarding the design of mesh products were excluded due to his lack of design experience.[18] Dr. Blaivas had specific experience in developing the autologous rectus fascial sling operation; however, this Court determined such experience did not make him an expert in design of a medical device.[19] Dr. Schwartz, who has no design experience and is further not an expert in design of medical devices, is unqualified to offer design opinions according to this Court's ruling in *Tyree*.[20]

Finally, Ethicon unsuccessfully attempts to distinguish Plaintiffs' reliance on this Court's Orders in both *Huskey* and *Wise* by contending that Dr. Michael Greenburg, a toxicologist whose opinions regarding degradation were excluded, and Dr. Marshall Austin, a pathologist whose opinions regarding design were excluded, are irrelevant to Dr. Schwartz as Ethicon claims this Court's determinations that a toxicologist unqualified to testify regarding degradation and that a pathologist is unqualified to offer design opinions irrelevant to the determination of whether a urologist such as Dr. Schwartz is qualified to do so.[21] Notwithstanding that Dr. Schwartz is unqualified to opine on the material properties of the TVT-O and TVT-Secur for the reasons previously stated above and in Plaintiffs' motion, Dr. Schwartz's qualifications and experience

[17] Pls.' Mem. at 5-6.
[18] *Tyree v. Boston Scientific Corp.*, 54 F.Supp.3d 501, 561 (S.D. W. Va. 2014)
[19] *Id.*
[20] *See id.*
[21] *Huskey*, 29 F. Supp. 3d at 725; *Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 570070, at *4 (S.D. W. Va. Feb. 11, 2015). Ethicon Response at 4.

clearly do not rise to the same level as these very experts who were excluded regarding degradation.[22]

Again, Dr. Schwartz's opinions regarding the design of the TVT-O and TVT-Secur are based predominately on his personal clinical experience. In light of his admitted lack of education, experience, training and knowledge as well as Ethicon's inability to demonstrate that his qualifications are consistent with those this Court previously deemed appropriate, Dr. Schwartz is unqualified and should not be allowed to testify regarding mesh degradation or particle loss or the design of the TVT-O and the TVT-Secur, specifically the topics of mechanical-cut v. laser-cut mesh; fraying, curling and roping; pore size and density. These opinions exceed the bounds of his qualifications and should be excluded.

II. DR. SCHWARTZ'S OPINION REGARDING DEGRADATION SHOULD BE EXCLUDED

Tellingly, Ethicon cites no authority for its contention that Dr. Schwartz's opinions regarding degradation are reliable despite the plethora of decisions from this Court on the subject. Dr. Schwartz bases his opinions regarding degradation on the fact that he "has not observed any clinically significant degradation of the TVT-O [or TVT-Secur] in my practice nor have I heard reports from colleagues."[23] Moreover, Dr. Schwartz only examines mesh grossly for purposes of evaluating whether the removed mesh has degraded.

> Q. And in the women who have come to you for treatment and you have removed mesh, have you examined that mesh for purposes of determining if it has degraded?
> A. Just gross inspection only.
> Q. And so if degradation is not possible to appreciate grossly, then you have never reviewed mesh for purposes of determining that it has degraded, true?
> A. I have never microscopically examined explanted mesh.

[22] *Huskey*, 29 F. Supp. 3d at 725; *Wise*, 2015 WL 570070 at *3-4.
[23] *See* Ex. B at 30; *See* Ex. C at 28-29.

> Q. And on what basis do you say, Dr. Schwartz, that TVT-O mesh does not degrade?
> A Once again, based on my clinical experience implanting and explanting the mesh and the long-term studies that look at the effectiveness. If the mesh degraded, the procedure efficacy would be dramatically different. And when I explant mesh, it looks very similar to when I implant the mesh, but I'm talking grossly.[24]

Dr. Schwartz bases his opinion that mesh does not degrade on the following: 1) his clinical experience (i.e., he opines if mesh degraded, surgeons would see it in their clinical practice and since he has not seen what he deems as evidence in his clinical practice, mesh must not degrade); 2) when he explants mesh and looks at it grossly he sees no evidence of degradation;[25] and 3) literature reporting the outcomes of clinical trials testing the efficacy of the products do not report degradation.[26]

This Court excluded Dr. Culligan's opinions regarding degradation for similar testimony where he based his opinion regarding degradation because he testified that degradation was not clinically meaningful and that the only assessed degradation grossly when he removed mesh.[27] For the same reasons, the Court should also exclude Dr. Schwartz's opinions regarding degradation.

III. DR. SCHWARTZ'S OPINIONS AND TESTIMONY REGARDING SHRINKAGE SHOULD BE EXCLUDED

Similarly, Ethicon cites no authority to support its argument that Dr. Schwartz's opinions regarding shrinkage should be allowed. In his report, Dr. Schwartz states that "I have not seen clinically significant contraction in the TVT-O [and TVT-Secur] mesh slings that I have used."[28] When asked what he had done to evaluate whether mesh shrinks, he replied, "clinical

[24] Ex. E at 77:7-20.
[25] Ex. E at 77:2-20.
[26] Ex. E at 77:12-20; 80:23-81:16.
[27] *Winebarger*, 2015 WL 1509362, at 35 (S.D. W. Va. April 1, 2015).
[28] Ex. B at 28; Ex. C at 28.

examination" but admitted he had made no effort during the examinations of his patients to evaluate any differences in the surface area of the mesh.[29] He did not perform vaginal ultrasounds.[30] He testified he had reviewed some studies that discussed shrinkage, but that he relied on literature that "attests to effectiveness" in reaching his conclusion that shrinkage of mesh does not have clinical significance.[31] Dr. Schwartz has not performed any studies to measure contracture of mesh.[32]

This Court has excluded the opinions of clinicians who opined regarding shrinkage or contracture when those opinions are based on their clinical experience and when the physician has not made any effort to evaluate shrinkage – *Tyree* (Blaivas); *Edwards* (Blaivas); *Frankum* (Margolis); *Wineberger* (Culligan, Goldberg); *Carlson* (Culligan). Plaintiffs urge the Court to do the same here and exclude Dr. Schwartz's opinions and testimony regarding shrinkage or contracture.

IV. DR. SCHWARTZ'S OPINION AND TESTIMONY REGARDING THE TVT-O AND TVT-SECUR'S INSTRUCTIONS FOR USE SHOULD BE EXCLUDED

Ethicon argues that Plaintiffs do not support with citations to Dr. Schwartz's testimony or to his reports in demonstrating that Dr. Schwartz's opinions regarding the IFUs should be excluded due to his unfamiliarity with the standards applicable to medical device IFUs or the processes for IFU development and approval.[33] This is absolutely incorrect. To avoid complete repetition, Plaintiffs reassert their memorandum in support of their motion here. Notwithstanding that, Dr. Schwartz admitted that his opinions regarding the IFUs were based on his personal experience and the personal experience of his colleagues, and that he had skimmed

[29] Ex. E at 69:7-70:13.
[30] Ex. E at 66:14-17.
[31] Ex E at 72:12-24.
[32] Ex. E at 75:11-15.
[33] Ethicon Response at 16.

the FDA's Device Labeling Guide and had only done so within the context of litigation. His testimony is conclusive:

> Q. **And is it your opinion that you outline here on what was not necessary to include in the IFU, based on your personal experience?**
> A. **And the experience of my colleagues as well.**
> Q. What colleagues are you referring to?
> A. My surgical colleagues.
> Q. Your partners?
> A. Yes.
> Q. In your medical practice?
> A. Yes.
> Q. Anything else?
> A. Basically surgeons in general.
> …..
> Q. I'm talking about a medical device, and all medical devices have IFUs, and I'm asking, when you say there is no need to put into an IFU known risks of procedure, **you've stated that you base that on your personal experience and talking with your colleagues. Is there anything else you base that opinion on?**
> **A. Not that I can think of currently.**[34]
>
> Q. Have you ever, sir, read that outside – read [FDA's Device Labeling Guide] outside of the context of litigation?
> A. No.
> Q. Have you read it inside the context of litigation?
> A. I have reviewed it.
> Q. **Is that a fancy way of saying you may have skimmed it?**
> A. **Yes**.[35]

In *Bellew v. Ethicon, Inc.*,[36] the Court excluded Dr. Denise Elser's opinions regarding an IFU. Dr. Elser is a board-certified urogynecologist and the Medical Director at the Women's Health Institute of Illinois. Dr. Elser testified that she based her opinions regarding the adequacy of the Prolift IFU on her clinical experience. The Court ruled that Dr. Elser's understanding of the possible risks associated with pelvic surgery is not enough to qualify her to offer opinions about the adequacy of the label. Also, in *Bellew*, the Court excluded the testimony of Dr.

[34] Ex. E 90:1-12; 90:19-91:1.
[35] Ex. E 135:22-136:5.
[36] No. 2:13-cv-22473, Order of Nov. 20, 2014, at p. 33 (S.D. W. Va.).

Christine Pramudji, also a board-certified urogynecologist, regarding the adequacy of the Prolift IFU on the same basis. In both instances, the Court quoted its decision in *Tyree* "that without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate, merely because it included the risk [s]he observed in [her] own practice."[37]

Dr. Schwartz readily admitted that he based his opinions regarding the TVT-O and TVT-Secur labels on his personal experience. "Skimming" the FDA guidance on labeling does not change that fact. Dr. Schwartz is not qualified to offer opinions regarding the adequacy of an IFU. Plaintiffs respectfully urge the Court to exclude Dr. Schwartz's opinions regarding the adequacy of the TVT-O and TVT-Secur IFUs.

V. DR. SCHWARTZ'S OPINIONS REGARDING ETHICON'S PROFESSIONAL EDUCATION PROGRAM SHOULD BE EXCLUDED

In both his TVT-O and TVT-Secur reports, Dr. Schwartz opines about his experience with Ethicon's professional education program.[38] When asked if he held an opinion regarding Ethicon's professional education program, Dr. Schwartz testified that he did not hold an opinion regarding the effectiveness of the program in relation to the products but only that he had had a positive experience.[39] Ethicon suggests in its Opposition that Plaintiffs misrepresented Dr. Schwartz's testimony regarding his opinions. This is not the case.

> Q. Are you going to opine, to a reasonable degree of medical certainty, that Ethicon provided adequate training to surgeons on the implantation of the TVT-O?
> A. Ethicon provided me with adequate training and I in turn provided other surgeons with adequate training.
> Q. Do you have any opinion as to the overall training provided by Ethicon to surgeons who purchase the TVT-O product?
> A. I cannot attest to what their experience was.

[37] *Tyree v. Ethicon, Inc.*, 54 F.Supp.3d 501, 584 (S.D. W. Va. 2014).
[38] Ex. B at 33; Ex. C at 33.
[39] *See* Ex. O at 58:24-59:9.

Q. You can only attest to your own experience?
A. Correct.
Q. Okay.[40]

Dr. Schwartz does not base his opinions on corporate documents or any other information evaluating the accuracy, comprehensive nature or effectiveness of Ethicon's training program. This Court has excluded expert opinion on training even when based on company documents.[41]

VI. DR. SCHWARTZ'S OPINIONS REGARDING THE SAFETY AND EFFICACY OF THE TVT-SECUR SHOULD BE EXCLUDED

In his report, Dr. Schwartz opines that the TVT-Secur is safe and effective.[42] The TVT-Secur is not a full-length mid-urethral sling, but rather a "mini-sling" that only requires one incision.[43] Dr. Schwartz cites a 2015 Cochrane Review entitled, "Mid-urethral sling operations for stress urinary incontinence in women."[44] He testified that the results of Ford 2015 Cochrane review could be extrapolated to the TVT-Secur and support a conclusion that the device is safe and effective. The Cochrane review Dr. Schwartz cited did not address the safety of the TVT-Secur or mini-slings in general. Rather, it addressed the safety and efficacy of full-length mid-urethral slings, such as the TVT and TVT-O.

Dr. Schwartz failed to cite or consider[45] the Cochrane review that actually addresses the safety and efficacy of mini-slings,[46] "Single-incision sling operations for urinary incontinence in women," published in 2014. In it, the authors conclude that, "[o]verall results show that TVT-

[40] Ex. E at 92:6-92:18.
[41] *Edwards v. Ethicon, Inc.*, 2014 WL 3361923, at *18 (S.D. W. Va. July 18, 2014).
[42] Ex. C at 19-24.
[43] Ex. C at 16-18.
[44] Ex. C at 21; Ford AA, et al., Mid-urethral sling operations for stress urinary incontinence in women. Cochrane Database of Systematic Reviews 2015, Issue 7. Art. No.: CD006375. DOI: 10.1002/14651858.CD006375.pub3. (Ex. U).
[45] *See* Ex. F at 37:2-41:19.
[46] Nambiar A, Cody JD, Jeffery ST. Single-incision sling operations for urinary incontinence in women. Cochrane Database of Systematic Reviews 2014, Issue 6. Art. No.: CD008709. DOI: 10.1002/14651858.CD008709.pub2 (Ex. P).

Secur is considerably inferior to retropubic and inside-out transobturator slings"; the "TVT-Secur is inferior to standard mid-urethral slings for the treatment of women with stress incontinence and has already been withdrawn from clinical use"; and "TVT-Secur is a specific type of mini-sling that has consistently been shown to provide poorer control of incontinence, along with higher rates of side effects, compared with standard mid-urethral slings. It has already been withdrawn from clinical use."[47]

Dr. Schwartz also failed to consider the following studies that conclude that the TVT-Secur is not effective (and in some instances not safe): Hota (2012); Cornu (2010); Barber (2012); and Masata (2012). These studies were not cited in Dr. Schwartz's report or listed on his reliance list. Ethicon admits that Dr. Schwartz was either not aware of the articles at the time that he wrote his report, he was given the article by Ethicon counsel, or he identified the article by a literature search (though it was not clear when the search was done). These facts provide insight into the unreliability of Dr. Schwartz's methodology.

The overwhelming weight of the published scientific literature establishes that the TVT-Secur is not effective and in some instances, not safe. Dr. Schwartz's opinions to the contrary are not based on scientific and medical literature, are unreliable, and should be excluded.

CONCLUSION

For the reasons above and those stated in Plaintiffs' motion and memorandum in support, the opinions offered by Brian N. Schwartz, M.D. do not meet the requirements for admission under the Federal Rules of Evidence and *Daubert*. As a result, they must be excluded.

[47] *Id.* at 3-4.

This 16th Day of May, 2016

By: /s/ P. Leigh O'Dell

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CERTIFICATE OF SERVICE

I hereby certify that on May 16, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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